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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

In re GILEAD SCIENCES SECURITIES LITIGATION	Master File No. C-03-4999-SI
	CLASS ACTION
	FIFTH CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF FEDERAL SECURITIES LAWS
This Document Relates To: ALL ACTIONS.	DEMAND FOR JURY TRIAL

SUMMARY AND OVERVIEW

1. Lead Plaintiffs Trent St. Clare and Terry Johnson ("Plaintiffs") bring this federal securities class action individually, and on behalf of a proposed class (the "Class") of all purchasers of the publicly traded securities of Gilead (NASDAQ: GILD) between July 14, 2003 and October 28, 2003, inclusive (the "Class Period"), against Gilead Sciences, Inc. ("Gilead" or the "Company") and certain of its top officers seeking remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Gilead, based in Foster City, California, is a biopharmaceutical company that discovers, develops, and commercializes pharmaceutical treatments for life-threatening diseases. According to Gilead's Forms 10-Q for the periods ending June 30, 2003 and September 30, 2003, the Company has six approved commercial products, including Viread, an antiretroviral agent used in combination with other drugs for the treatment of HIV infection. At all relevant times, Viread product sales are approximately 65% of Gilead's total revenues.

3. As stated in Gilead's Form 10-K for the period ending December 31, 2002 ("2002 10-K"), filed with the United States Securities and Exchange Commission ("SEC") on March 14, 2003, Gilead's commercial teams "promote Viread . . . through direct field contact with physicians, hospitals, clinics and other healthcare providers who are involved in the treatment of patients with HIV."

4. Throughout the Class Period, Defendants knowingly and affirmatively misrepresented the most important measurement of Gilead's performance and prospects to the investing public: the nature and cause of its increased sales of Viread. Wall Street analysts looked to sales of Viread, Gilead's most important and most promoted drug, to gauge whether the Company's business was on track and growing. If Gilead failed to publicly report healthy, growing Viread sales, its stock price would be greatly diminished.

5. Indeed, in an October 28, 2003 press release, Defendant and CEO John C. Martin ("Martin") addressed Gilead's need to obtain "higher prescription volumes" for Viread and identified the "important demand indicators" for Viread as being "new and total prescriptions." Thus, according to the 2002 10-K, Gilead had to "maintain and expand its position in the

marketplace" (2002 10-K at 24) in the following areas: "efficacy; safety; tolerability; acceptance by doctors; patient compliance; patent protection; ease of use; price; insurance and other reimbursement coverage; distribution; marketing; and adaptability to various modes of dosing." *See* 2002 10-K at 18.

6. In an October 27, 2003 *Forbes* article, Defendant Martin acknowledged that in order for Gilead to reach its goal of increasing new and total prescriptions, it had to convince physicians to switch patients from a competitor's drugs to Gilead's Viread drug regimen. According to the article, Defendant Martin "concedes this is driven by marketing: 'The AIDS market is driven by data.'" Thus, according to the author, "Gilead, lacking a big ad budget, woos doctors by putting out a slew of data showing Viread to be more effective than [competitor drugs], with fewer nasty side effects."

7. In accordance with their business plan, Defendants made certain that Gilead reported extremely impressive Viread sales results during the Class Period. Unfortunately for investors, these results were attained through Defendants' campaign of false and misleading promotional activities for Viread found to be in violation of the Federal Food, Drug and Cosmetic Act and its implementing regulations by the U.S. Food and Drug Administration ("FDA"). This off-label marketing scheme materially (albeit artificially) increased Viread sales and created a false demand for Viread. This skewed demand, in turn, motivated wholesalers to overstock massive amounts of Viread in anticipation of an announced price increase.

8. To successfully implement their campaign of false and misleading promotional activities, both prior to and during the Class Period, Defendants engaged in a systematic plan to market Viread using clinical studies and other materials that had not received FDA approval and by inducing Gilead sales and marketing representatives to make false and misleading statements concerning Viread's safety and efficacy to physicians, health care professionals and others. Such tactics are generally referred to as "off-label marketing." In doing so, Defendants minimized important risk information regarding Viread, promoted Viread on the basis of unproven and untested theories, and illegally "broadened the indication" for prescribing Viread to patients in violation of FDA regulations by, among other things: (1) promoting it for use in patients with Hepatitis B co-infection, despite the fact that it was not approved for such use; and (2) promoting Viread as an

"initial" or first-line treatment for HIV, even though, as discussed in more detail below, the FDA did not approve Viread for such treatment until late 2003. On two occasions, the FDA ordered Gilead to cease and desist this practice. Gilead blatantly ignored the FDA's first warning (in a March 2002 FDA Untitled Letter) and thus received the second, more dire, warning from the FDA in July 2003 (during the Class Period). Defendants' false, misleading, and illegal promotional practices resulted in materially increased sales of Viread during, at least, the Class Period.

9. Indeed, Gilead's off-label and illegal promotional practices led to increased prescriptions which enabled Defendants to create the false and misleading impression that demand for Viread was much stronger than it actually was during the Class Period. As acknowledged by Defendants, increased Viread prescriptions were the primary indicator of strong Viread demand. Defendants, however, misled the market as to the true demand for Viread by failing to disclose that between 75% - 95% of all sales of Viread were caused by off-label marketing. Given Gilead's domestic Viread sales of $115.6 million and $59.4 million during the second and third quarters of 2003, respectively, this means that between $86.7 million and $108.92 million (second quarter 2003) and between $44.5 million and $56.43 million (third quarter 2003) of domestic Viread sales reported during the Class Period were attributable to the off-label marketing scheme. In short, the market was not told that off-label marketing was the cornerstone of demand and defined the culture of the Company. This mistaken impression of demand led to, among other things, wholesaler overstocking in reaction to an anticipated price increase. When the truth about Defendants' off-label marketing was disclosed, however, Defendants could no longer maintain the sales growth levels that investors had come to expect, and Gilead's stock price dropped accordingly.

10. At the beginning of the Class Period, Gilead announced that overall sales doubled during Second Quarter of 2003, year-over-year, largely on the strength of Viread sales. The news caused Gilead's stock price to rise $7.97 in one day, to a near-record high of $67.25.

11. However, securities analysts observed that the apparent strong demand for Viread resulted in part from wholesalers stocking up on the drug ahead of a price increase announced by Gilead in June 2003. The analysts were concerned that in future quarters demand for Viread would be met by inventory stocked by the wholesalers, rather than by new sales.

12. Indeed, in order to sell their stock at artificially inflated prices and to sustain the false and misleading impression that demand for Viread was strong, Defendants unequivocally rebutted the analysts' concerns. Defendants represented that the strong Second Quarter 2003 Viread sales were due to "an increase in prescriptions, not inventory stocking" and that "increased stocking by U.S. wholesalers accounted for $25-$30 million of Viread sales." Because Defendants did not reveal that the "demand" for Viread was the result of off-label marketing, Defendants' rebuttal masked the fact that they would not be able to keep up sales growth at the same rate that investors had come to expect. Thus, as wholesalers drew down their overstocking in response to decreased demand, results would ultimately be worse than the market anticipated.

13. Defendants' inflated claims about Viread had their intended effect of maintaining Gilead's stock price long enough for Defendants to dump their Gilead shares on an unsuspecting market.

14. In just twenty-four days (between August 5, 2003 and August 29, 2003), Defendants sold in excess of 300,000 shares of Gilead stock at artificially inflated prices, reaping gross proceeds in excess of $20 million. This was the first and only time when all of the Defendants sold their stock during one coordinated time period. Notably, Defendants' selling spree took place just days after they had received FDA notification (sent to Gilead, care of Defendant Martin on July 29, 2003, but not made public until August 7, 2003) – for the second time since the launching of Viread – that their Viread promotional campaign and off-label marketing practices violated federal law. As set forth below, the disclosure of the existence of the FDA Warning Letter set in motion events that would impede Viread's sales growth and ultimately result in a sharp drop in Gilead's stock price.

15. At the end of the Class Period Defendants announced that sales of Viread in Third Quarter 2003 would be materially less than previously indicated. During the Third Quarter of 2003, wholesalers, responding to decreased demand for Viread after the disclosure of the FDA Warning Letter, drew down the entire amount of overstock and their existing supplies rather than purchase additional Viread. In short, demand for Viread was not nearly as strong as Defendants had led the market to believe.

16. In reaction to Gilead's announcement of disappointing third quarter results, the price of Gilead stock plummeted, falling $7.46 in one day, from $59.46 per share on October 28, 2003, to $52 per share on October 29, 2003.

JURISDICTION AND VENUE

17. Plaintiffs bring this action pursuant to §§10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") (15 U.S.C. §§78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

18. This Court has jurisdiction over the subject matter of this action pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1331.

19. Venue is proper in this District pursuant to §27 of the Exchange Act, 15 U.S.C. §78aa and 28 U.S.C. §1391(b). At all times relevant to this action, Gilead maintained its principal place of business in this District and many of the acts and transactions alleged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District.

20. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications, and the facilities of the national securities markets.

THE PARTIES

Plaintiffs

21. Plaintiffs Trent St. Clare and Terry Johnson purchased Gilead securities on the open market during the Class Period as set forth in their certifications previously filed with the Court. The Court's January 30, 2004 Order appointed St. Clare and Johnson as Lead Plaintiffs in this consolidated action.

Defendants

22. Defendant Gilead, a Delaware corporation, maintains its principal place of business at 333 Lakeside Drive, Foster City, California 94404. Gilead is a biopharmaceutical company that discovers, develops, and commercializes therapeutics to advance the care of patients suffering from

life-threatening diseases worldwide. The Company has six commercial products including Viread, an antiretroviral agent used in combination with other drugs for the treatment of HIV infection.

23. During the Class Period, Defendant Martin was the Company's President and Chief Executive Officer.

24. During the Class Period, Defendant John F. Milligan ("Milligan") was the Company's Chief Financial Officer and Senior Vice-President.

25. During the Class Period, Defendant Mark L. Perry ("Perry") was the Company's Executive Vice-President, Operations.

26. During the Class Period, Defendant Norbert W. Bischofberger ("Bischofberger") was the Company's Executive Vice-President, Research and Development.

27. During the Class Period, Defendant Anthony Carraciolo ("Carraciolo") was the Company's Vice-President.

28. During the Class Period, Defendant William A. Lee ("Lee") was the Company's Senior Vice-President, Research.

29. Martin, Milligan, Perry, Bischofberger, Carraciolo, and Lee (collectively the "Individual Defendants") were privy to non-public information concerning Gilead's business, finances, sales, products, product marketing and promotion, and present and future business prospects via access to internal corporate documents, conversations, and connections with other corporate officers and employees, attendance at sales management and Board of Directors meetings and committees thereof, and via reports and other information provided to them in connection therewith. Because of their possession of such information, the Individual Defendants knew or with deliberate recklessness disregarded the fact that adverse facts specified herein had not been disclosed to, and were being concealed from, the investing public. Except to the extent set forth in this Complaint as provided by confidential witnesses who are primarily former Gilead employees, Plaintiffs and other members of the Class had no access to such information, which was, and remains solely under the control of Defendants. The Individual Defendants were involved in drafting, producing, reviewing, and/or disseminating the materially false and misleading statements complained of herein. The Individual Defendants were aware (or disregarded with deliberate

recklessness) that materially false and misleading statements were being issued regarding the Company and nevertheless approved, ratified, and/or failed to correct those statements, in violation of the federal securities laws.

30. Throughout the Class Period, the Individual Defendants were able to, and did, control the contents of the Company's SEC filings, reports, press releases, and other public statements. The Individual Defendants were provided with copies of, reviewed and approved, and/or signed such filings, reports, releases, and other statements prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. The Individual Defendants also were able to, and did, directly or indirectly, control the conduct of Gilead's business, the information contained in its filings with the SEC, and its public statements. Moreover, the Individual Defendants made or directed the making of affirmative statements to securities analysts and the investing public at large, and participated in meetings and discussions concerning such statements. Because of their positions and access to material non-public information available to them but not the public, each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations that were being made were then false and misleading. As a result, each of the Individual Defendants is responsible for the accuracy of Gilead's corporate releases detailed herein as "group-published" information and is therefore responsible and liable for the representations contained therein.

31. Each of the Defendants is liable as a primary violator in making false and misleading statements, and for participating in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Gilead securities during the Class Period. All of the Defendants had motives to pursue a fraudulent scheme in furtherance of their common goal, *i.e.*, inflating the trading price of Gilead securities by making false and misleading statements and concealing material adverse information. The fraudulent scheme and course of business was designed to and did: (i) deceive the investing public, including Plaintiffs and other Class members; (ii) artificially inflate the price of Gilead securities during the Class Period; (iii) cause Plaintiffs and other members of the Class to purchase Gilead securities at inflated prices; and (iv) allow Gilead to conceal and cover up

the true financial condition of Gilead to the detriment of its investors, but to the financial benefit of the Individual Defendants.

CLASS ACTION ALLEGATIONS

32. Plaintiffs bring this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of the Class, consisting of all those who purchased the securities of Gilead during the Class Period. Excluded from the Class are Defendants, the officers and directors of the Company, members of their immediate families and their legal representatives, heirs, successors, or assigns and any entity in which Defendants have or had a controlling interest.

33. Because Gilead has millions of shares of stock outstanding, and because the Company's shares were actively traded, members of the Class are so numerous that joinder of all members is impracticable. As of February 27, 2004, Gilead had over 213 million shares outstanding. While the exact number of Class members can only be determined by appropriate discovery, Plaintiffs believe that Class members number at least in the thousands and that they are geographically dispersed.

34. Plaintiffs' claims are typical of the claims of the members of the Class, because Plaintiffs and all of the Class members sustained damages arising out of Defendants' wrongful conduct complained of herein.

35. Plaintiffs will fairly and adequately protect the interests of the Class members and have retained counsel experienced and competent in class actions and securities litigation. Plaintiffs have no interests that are contrary to or in conflict with the members of the Class they seek to represent.

36. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy, since joinder of all members is impracticable. Furthermore, as the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation make it impossible for the members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

37. Questions of law and fact common to the members of the Class predominate over any questions that may affect only individual members, in that Defendants have acted on grounds generally applicable to the entire Class. Among the questions of law and fact common to the Class are:

(a) whether Defendants violated the federal securities laws as alleged herein;

(b) whether Defendants' publicly disseminated press releases and statements during the Class Period omitted and/or misrepresented material facts;

(c) whether Defendants breached any duty to convey material facts or to correct material acts previously disseminated;

(d) whether Defendants participated in and pursued the fraudulent scheme or course of business complained of;

(e) whether Defendants acted willfully, with knowledge or deliberate recklessness, in omitting and/or misrepresenting material facts;

(f) whether the market prices of Gilead securities during the Class Period were artificially inflated due to the material nondisclosures and/or misrepresentations complained of herein; and

(g) whether the members of the Class have sustained damages and, if so, what is the appropriate measure of damages.

CONFIDENTIAL WITNESSES

38. Plaintiffs' allegations herein, concerning the falsity of Defendants' statements and the scienter of the Individual Defendants, are based upon, in part, interviews with former Gilead employees, including former members of the Company's sales and marketing staff. These witnesses, who spoke to Plaintiffs' counsel on a confidential basis, are referred to herein as Confidential Witnesses (hereinafter, "CW__") numbers 1 through 8. The positions that the Confidential Witnesses held at Gilead permitted them to have direct access to the information provided by each, as described below.

39. CW1 worked as a Gilead Therapeutic Specialist from 2001 until approximately May 2003. As a Therapeutic Specialist, CW1 was responsible for promoting, marketing, and selling

Gilead products, namely Viread, and regularly had contact with and exposure to numerous Gilead executives and Regional Directors, including the Individual Defendants (with the exception of Carraciolo). CW1's territory covered the Indiana, Illinois, and Michigan markets. In the course of his or her regular duties, CW1 worked with a variety of healthcare professionals, including physicians, nurses, social workers, and patients. In addition, over the course of CW1's employment with Gilead, CW1 attended and participated in numerous national and regional Gilead meetings wherein Gilead executives specifically discussed the promotion of Viread. At these meetings, as well as at other times, Gilead provided CW1 with detailed information on Viread and told CW1 to use that information to aggressively promote and sell Viread. Among the information provided, however, was information not approved by the FDA for use in marketing and promoting Viread. Gilead executives provided this off-label information despite knowing that off-label marketing violated FDA rules and regulations. Further, at various times during CW1's employment with Gilead, Gilead executives specifically instructed CW1 to teach and train other members of Gilead's sales and marketing staff how to improperly and illegally use off-label information to market Viread.

40. Prior to the Class Period, CW1 was a member of Gilead's Field Marketing Advisory Committee, a select committee of Gilead sales and marketing staff that periodically met to discuss theories and strategies for marketing and selling Viread. This elite group of Gilead employees was responsible for monitoring and shaping Gilead's marketing efforts and advising Gilead's management of the progress of those efforts. Members of Gilead's sales and marketing staff from various regions of the country, as well as high-ranking Gilead officers and executives, including, but not limited to, Michael Inouye ("Inouye"), Gilead's Senior Vice-President of Commercial Operations, James Meyers ("Meyers"), Gilead's Vice-President of U.S. Sales, and various heads of marketing, such as Debbie Fletcher ("Fletcher") and Sheryl Meredith ("Meredith") attended the Field Marketing Advisory Committee meetings. As a result of CW1's membership on the Field Marketing Advisory Committee, and CW1's other contact and communications with numerous Gilead sales people, CW1 was very familiar with the sales tactics employed Company-wide and the impact of those tactics generally (and off-label marketing specifically) on Viread sales.

41. During the course of his or her employment, CW1 reported directly to Gary DelloStritto ("DelloStritto"), Gilead's Regional Director for the Mid-West. In turn, DelloStritto reported to Meyers, Gilead's Vice-President of U.S. Sales, who reported to Shay Weisbrich ("Weisbrich"), Gilead's Vice-President of Sales and Marketing. Both Meyers and Weisbrich were members of Gilead's Senior Management Team. Ultimately, Weisbrich was responsible to Inouye, Gilead's Senior Vice-President of Commercial Operations and a member of the Executive Committee. Lastly, Inouye reported to the Individual Defendants, including Defendant Martin, and the Board of Directors.

42. CW2 worked as a Gilead Therapeutic Specialist from July 2000 until approximately February 2004. As a Therapeutic Specialist, CW2 was responsible for promoting, marketing, and selling Gilead products, namely Viread, and worked with a variety of healthcare professionals, including physicians, nurses, social workers, and patients in a manner similar to CW1. CW2 was, at various times throughout his or her tenure, responsible for covering the Georgia, South Carolina, and Alabama markets.

43. CW2 began his or her career at Gilead in the South sales region. During that time, CW2 reported to Bill Rich ("Rich"), Gilead's Regional Director for the South. In turn, Rich reported to Meyers, who reported to Inouye. Lastly, Inouye reported to the Individual Defendants, including Defendant Martin, and the Board of Directors.

44. During CW2's employment, CW2 also was a member of Gilead's Dallas region and Southeast regions. While a member of Gilead's Dallas and Southeast regions, CW2 reported to Kirk Kaiser ("Kaiser"), a Gilead Regional Director, and later to Charles Packard ("Packard"), another Gilead Regional Director. Kaiser and Packard reported to Rich. Rich, in turn, reported to Meyers. Finally, Meyers reported, at various times, to either Weisbrich or Fletcher (who replaced Weisbrich) and Inouye.

45. CW2 participated in pre-launch training for Viread, including, but not limited to, Gilead seminars and Gilead home-study materials. According to CW2, during the pre-launch period, Gilead was unsure whether the FDA would approve Viread and, if so, whether the approved indication(s) for Viread would be broad or limited. CW2 explained that if the FDA approved Viread

it could be for the use of Viread over a spectrum of indications from a "salvage" indication to an "experienced" indication to a "naïve" indication. A "salvage" indication would limit Viread's use to patients with long-term HIV infection. An "experienced" indication would allow Viread's use by patients previously treated with other HIV drugs. Finally, a "naïve" indication would mean that Viread could be used by patients recently infected with HIV but not yet exposed to a diverse treatment regimen. The "naïve" indication is broader than the "experienced" indication and much broader than the "salvage" indication. Gilead wanted a "naïve" indication which would allow for much higher levels of Viread sales. CW2 estimates that seventy percent (70%) of AIDS drugs are sold to "naïve" and "experienced" patients, while only thirty percent (30%) are sold to "salvage" patients. CW2 also had a large amount of contact with CW2's peers – other Viread sales people. In fact, Gilead's sales force, including CW1 and CW2, routinely shared information regarding their sales tactics, the latest information being pushed by Gilead, and their sales. As a result, CW2 knows that other sales people, at the insistence of Defendants, utilized off-label marketing and materially increased Viread sales during the Class Period.

46. While awaiting FDA approval, and while not knowing what indication Viread might receive, Gilead taught its sales staff to prepare to market Viread as though it had been approved with the broadest possible indication. According to CW2, Gilead's earliest plans included a scheme to market Viread to "naïve" and "experienced" HIV patients regardless of the breadth of FDA approval.

47. Over the course of his or her employment with Gilead, CW2, like CW1, attended and participated in numerous national and regional Gilead meetings wherein Gilead executives specifically discussed the promotion of Viread. At these meetings, as well as at other times, Gilead executives provided CW2 with detailed off-label information for Viread and told CW2, both overtly and covertly, to use that information to aggressively promote and sell Viread despite the fact that those executives knew that such off-label marketing violated the FDA's rules and regulations.

48. Nevertheless, despite his or her superiors' pressure to market Viread utilizing off-label materials, CW2 attempted to utilize off-label materials as little as possible. As sales people in other areas of the country utilized off-label materials, however, the gap between sales in CW2's

territory and other territories widened. Defendants then increased the already substantial pressure on CW2 to use off-label marketing. CW2 succumbed to this pressure, and did so in order to save his or her job and attempt to satisfy Defendants. Ultimately, CW2 terminated his or her employment with Gilead rather than follow these repeated directives to increase his or her use of off-label materials.[1]

49. CW3 worked for Gilead from 2000 until January 2005. This former employee worked as a Gilead Therapeutic Specialist in the Washington state area, which included Seattle, Washington, from 2000 until late 2002. During this time, CW3 reported to Regional Director David McCullough ("McCullough"). As a Therapeutic Specialist, CW3 was responsible for selling Viread, Hepsera, and AmBisome.

50. In late 2002, CW3 was promoted to the role of Training Manager to replace Trainer Kristin Bennett ("Bennett"), who was promoted to the position of Senior Sales Director. Upon CW3's promotion to Training Manager, CW3 began working at the Company's Foster City, California headquarters. At the same time, another former Therapeutic Specialist was also assigned the role of Training Manager. Both CW3 and the other Training Manager reported to Meyers, the

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[1] In Plaintiffs' Consolidated Amended Class Action Complaint for Violation of Federal Securities Laws filed April 30, 2004 [DE #50] (the "CAC"), it was alleged that CW2 refused her/his "superiors' ever-increasing pressure to market Viread utilizing off-label materials" and "terminated his or her employment rather than follow these questionable directives to use off-label materials." CAC at ¶50. This allegation incorrectly implied CW2 never promoted or sold Viread with off-label information. Subsequent to the Court's January 26, 2005 Order [DE #98] dismissing without prejudice the CAC, as part of Plaintiffs' ongoing investigation, CW2 continued to describe her/his experiences at Gilead. During this time, CW2 clarified what she/he meant by CW2's "refusal" to bow to her/his superiors' ever-increasing pressure to market Viread with off-label information, and provided further explanation and factual detail concerning her/his resignation from Gilead. CW2 stated that she/he had no choice but to engage in off-label marketing while at Gilead. CW2, however, was never comfortable doing so because CW2 knew off-label marketing was illegal. Gilead management and CW2's superiors, however, pressured CW2 to utilize more and additional off-label materials. Put simply, CW2 was told she/he was not being aggressive enough with her/his use of off-label information to sell Viread and had to do more. Rather than kowtow to this additional pressure, CW2 left the Company. Thus, when CW2 stated that she/he refused to bow to "ever-increasing pressure" to market Viread using off-label information, CW2 did not mean she/he never used off-label information, but that she/he refused to increase her/his use of off-label information to sell Viread. Viewed in this light, allegations attributed to CW2 in the CAC and the Fourth Amended Consolidated Complaint ("FAC") are not contradictory. If anything, the original allegations in the CAC were inartfully drafted. To the extent the Court concludes they are conflicting, however, CW2's last word to Plaintiffs' counsel regarding sales of Viread and the reason why she/he left Gilead is reflected in the allegations of the FAC.

Company's Vice President of U.S. Sales. Around the time CW3 was promoted to the role of Training Manager in late 2002, the Company's sales force was divided up so that there were dedicated Therapeutic Specialists selling Viread and different Therapeutic Specialists selling Hepsera and AmBisome. From the time CW3 was promoted to Training Manager until she/he left the Company in 2005, CW3 was tasked with developing training materials for HIV Therapeutic Specialists – both incumbent and incoming Gilead sales representatives.

51. CW3 emphasized there was a pervasive, covert strategy throughout her/his tenure with Gilead to market Viread off-label and that this strategy was executed from the top-down. While working as a Therapeutic Specialist, CW3 promoted Viread for off-label indications using materials provided by CW3's superiors, which CW3 understood had been distributed to all of the HIV Therapeutic Specialists at Gilead for sales purposes. She/he stated that during the Class Period, Viread was promoted off-label for a treatment naïve indication, as well as for a Hepatitis B indication, and as having a better safety profile than was actually the case. CW3 stated the FDA, at the time, did not approve or allow any of this information to be used to sell Viread.

52. CW3 recalled there was widespread, covert encouragement by senior Company management to promote Viread off-label, and that off-label information and data was used by Therapeutic Specialists in sales calls throughout CW3's tenure. Among many other things, CW3 recalled that materials were presented and distributed to the Company's sales force at Gilead's national and regional sales meetings, and that these materials contained facts about the efficacy of Viread for treatment naïve patients and for the treatment of Hepatitis B – namely for co-infected patients. For example, CW3 stated that sales of Viread for use by treatment naïve patients represented a "large portion" of Viread sales before and during the Class Period, which resulted from Gilead's off-label promotion of Viread for such purposes. As a Therapeutic Specialist, CW3 experienced first-hand Defendants' off-label marketing scheme, and stated the strategy to promote Viread off-label was definitely covert, but also definitely one that spanned the ranks of the Company's sales and marketing departments, and defined the culture of the Company.

53. In her/his role as a Training Manager, CW3 was tasked with, among other things, writing-up materials for use by the Company's Therapeutic Specialists in their presentations to

doctors that contained both information approved by the FDA and unapproved off-label information from recent conferences and studies. CW3 stated that because Gilead's marketing department could not directly tell the sales force to market off-label, Gilead used the training department to deliver marketing's message. The result was that Gilead HIV Therapeutic Specialist training materials, including throughout the Class Period, contained a great deal of off-label information, and these training materials were provided to the Company's sales force specifically for use as talking points with the doctors on which they called. In addition, Meyers directed CW3 to write training materials for the Therapeutic Specialists that contained bullet points layered not only with FDA-approved data, but also with unapproved, off-label data and information. As a result, the Company's sales force was deliberately being trained and encouraged – from the highest levels – to engage their existing and potential clients in off-label discussion regarding Viread using information in the documents they received from the Company. Put simply, the internal Company strategy to sell Viread relied extensively on off-label information and data.

54. CW3 also stated that from at least the time CW3 was promoted in late 2002 through at least January 2005, there were weekly internal Gilead meetings to discuss the provision of off-label material to the Company's HIV sales force. These meetings were held in a conference room at the Company's home office in Foster City, California, and attendees at the meetings included the marketing and training department heads, the sales directors, and Meyers was typically brought in at the end of each meeting. The result of the meetings was that Meyers supported the notion that Therapeutic Specialists should receive off-label marketing materials, and directed the provision of such materials to be accomplished through the Company's training department. In other words, the training department's role in the Company's off-label marketing strategy would be to deliver marketing's off-label message. CW3 described her/his own specific role in the provision of off-label materials as part of the "whole wink and nod" process to give Gilead's sales team information they needed to market and sell Viread off-label.

55. By 2005, CW3 could no longer tolerate the ongoing unethical sales practices and consistent pressure to engage in the Company's illegal, off-label strategy to sell Viread. Put simply, the regular and constant internal pressure for CW3 to be the messenger of the Company's illegal off-

label marketing strategy became too much to bear. Rather than continue on the path cut by Defendants, CW3 left the Company.

56. CW4 was one of the members of the first group of Medical Science Liaisons to work for Gilead. CW4, a Ph.D., began her/his employment with the Company in approximately 1999 and was asked to leave the Company in approximately January 2003, when it was apparent CW4 was not willing to comply with some of the requests of the Company's senior management and sales organization to promote Viread in a biased, off-label manner. CW4 was hired by and initially reported to Vice President of Marketing Bruno Delagneau ("Delagneau"), who oversaw Gilead's Medical Science Liaisons until he was reassigned within Gilead. Steve Barriere ("Barriere") replaced Delagneau for approximately six months, at which time Barriere was removed and replaced by Chris Garabedian ("Garabedian").

57. CW4 stated Gilead promoted Viread off-label via presentations the Therapeutic Specialists made to medical practitioners, as well as through encouraging the Medical Science Liaison staff to act in a sales capacity, including presenting biased and unbalanced information about Viread. CW4 stated Viread was promoted off-label for a treatment naïve indication, a Hepatitis B indication, and as having a better safety profile than data suggested was actually the case. CW4 was aware that Therapeutic Specialists promoted Viread off-label based on her/his participation in meetings the Therapeutic Specialists had with HIV treating physicians. She/he stated that most of the Therapeutic Specialists who marketed Viread utilized off-label information, including through the use of documents provided to them by higher-level Gilead employees in briefing binders the sales force received at national Company meetings. CW4 emphasized that during the Class Period, government rules dictated the Therapeutic Specialists were not supposed to ask leading questions that could potentially result in an off-label discussion and were not legally allowed to talk about published data that had not been approved by the FDA. In other words, the rules were that Gilead's sales force was supposed to stay on-label. For example, if a practitioner had an off-label question, the Medical Science Liaisons were supposed to answer such questions in lieu of the Therapeutic Specialists, and were supposed to provide unbiased information about Viread. But, CW4 stated that "all of the [sales] reps" engaged in off-label detailing of Viread, and answered off-label questions on

their own without involving the Medical Science Liaison staff. Towards the end of her/his tenure with Gilead, CW4 recalled there were only approximately two Therapeutic Specialists who would excuse themselves from the discussion between their customers and CW4 when the subject turned to off-label areas – even though this should have been standard protocol so that the sales staff was not trying to close a sale with the help of the Medical Science Liaison staff.

58. On top of the foregoing, CW4, even though she/he was a Medical Science Liaison, was tasked with selling Viread at least 75% of the time, which was not consistent with what CW4's role should have been as a member of the medical affairs organization at Gilead. Instead of only presenting data at dinner meetings and Company meetings, and being available to address questions posed by investigators working on trials related to Viread or who were potentially interested in doing so, CW4 worked in a sales capacity. In this role as a Viread salesperson, CW4 was asked to promote Viread off-label. For example, the Medical Sciences Liaisons were encouraged to present data in a biased manner – namely in a manner that was not only off-label, but also made Viread appear to have a wider indication and a better safety profile than was actually the case. The pressure for the Medical Science Liaisons to act in a sales role and to present biased and off-label data for Viread while acting in a sales role came from the highest levels of senior management at Gilead. CW4 stated that Martin, the Company's CEO, led the off-label detailing strategy regarding Viread. CW4 also stated the Company's strategy to market Viread off-label was very covertly executed. She/he stated there was an "obvious push by top management," including Martin, to involve the Medical Science Liaisons in marketing and sales, including off-label sales of Viread. She/he stated that most of the Therapeutic Specialists complied with the Company's off-label marketing strategy – *i.e.*, they promoted and sold Viread with off-label information. CW4 stated those Therapeutic Specialists and, especially, the Medical Science Liaisons who were not willing to toe the Company line and follow Defendants' off-label selling strategy were ousted from the Company. These employees were shown the door and told they did not meet the Company's requirements.

59. CW4 was presented with an offer to leave Gilead in approximately 2003 because CW4 was not willing to promote biased "investigator initiated trials" for Viread led by Sales Director Helen Harris' staff. CW4 and her/his colleagues were replaced by medical doctors who

CW4 and her/his colleagues had formerly been calling on in their Medical Science Liaison roles to promote Viread. The Medical Science Liaisons that replaced CW4, Sass, and Childs included Bruch Olmscheid ("Olmscheid"), Al Fisher ("Fisher"), and Stuart Burstin ("Burstin").

60. CW5 worked for Gilead from 2001 through 2005, and is a former Therapeutic Specialist and Training Manager. CW5 was promoted to the role of Training Manager in late 2002. This former employee experienced the Company's off-label marketing scheme for Viread, and has knowledge concerning how it was implemented. CW5 stated there was a culture at Gilead that promoted and condoned off-label marketing of Viread throughout the Class Period. She/he based this statement on the fact that she/he had a lot of experience with the Company, first "in the field" and later in the corporate training role where she/he worked on the development and distribution of training materials for the sale of Gilead pharmaceuticals, including Viread. Based on her/his experiences with Gilead, CW5 stated the Company's strategy to market Viread off-label was developed and driven from the top executives, including the Vice President of U.S. Sales, Meyers.

61. For example, CW5 stated the Gilead HIV Therapeutic Specialists were provided with off-label marketing materials for use in promoting Viread, as well as being trained to be very aggressive in their sales pitches. CW5 recalled receiving off-label promotional materials that were not marked as being confidential or not for promotional use. When promoting Viread, the Company's Therapeutic Specialists were allowed and encouraged to use these materials in discussions with doctors.

62. Through discussions with the Company's Vice President of U.S. Sales, Meyers, CW5 learned that one way Gilead executed its off-label promotion strategy was through instilling the notion that the sales team members were "specialty care representatives" and that they were thus not limited to talking about just what was in the package insert for Viread. Meyers informed CW5 in discussions that as "specialty care reps," the Gilead Therapeutic Specialists were expected to be equipped and willing to engage in off-label discussion about Viread.

63. CW5 recalled there was a slide presentation developed by Meyers and presented by Rich, the Regional Director for Gilead's South Region, in April 2003. One particular slide in the presentation centered on the strategy to promote Viread off-label, and included details about

Gilead's efforts to use Medical Science Liaisons in a sales capacity to promote Viread off-label. This slide was shown at a sales meeting attended by the Southwest and Northeast Region sales team members and was part of a presentation detailing Gilead's strategy for "re-launching" Viread and bridging the gap between a slowdown in sales of Viread that had occurred prior to April 2003 and when Gilead anticipated receiving approval for the treatment naïve patient indication. CW5 stated the presentation may have also been made to new hires at the Company who were tasked with selling Viread and who were hired by Gilead during the first half of 2003.

64. CW5 stated the slide in question indicated that the Company needed to promote Viread to HIV doctors who were using it to treat Hepatitis-B – even though such promotional practices and concomitant sales were 100% off-label and illegal. CW5 stated the slide concerned the threat to Viread sales, meaning that the reason for the presentation in April 2003 was to deliver the message that sales of Viread were being threatened by HIV drugs developed and marketed by Gilead's competitors and that Gilead needed to market Viread for off-label indications as a means to overcome that threat. CW5 stated the Company's sales force was anxious to make sales and goose up Gilead's stock price, and thus were amenable to management's demand to sell off-label. Now that CW5 has left Gilead, however, she/he sees how egregious behavior was the norm at Gilead.

65. CW5 stated another example of the emphasis on off-label marketing at Gilead was the briefing binders or "poster books" put together for the sales force by the Company's trainers and sales managers. The briefing binders were comprised of abstracts collected from recent (at the time) medical conferences and other literature supporting and promoting Viread for various off-label indications. Trainers used these briefing binders, which doubled as visual aids, to teach sales representatives how to sell Viread for off-label uses. These "poster books" were provided to the Viread Therapeutic Specialists for use in the field, and the documents in them did not bear markings rendering them confidential or not for promotional purposes. CW5 stated the documents went beyond information approved by the FDA and the use of the "poster books" in field visits with practitioners constituted off-label marketing. She/he stated this off-label strategy was executed in such a manner that the Therapeutic Specialists would not only be equipped with materials to promote

Viread off-label, but also with the understanding that they were expected to promote the drug for off-label indications.

66. CW5 recalled that some sales representatives balked at the Company's off-label strategy for sales, but Meyers told CW5 directly that Defendant "John [Martin] would have people's heads on a platter if they didn't sell this way." Meyers was always telling CW5 to promote off of the data that was coming out of the conferences – *i.e.*, the off-label, non-FDA approved data. CW5 stated Gilead was a data-driven company, and the sales force was taught to sell from the off-label data. CW5 recalled that Meyers was duplicitous and would not say anything about off-label marketing at the Company's conferences, but was a very different person behind closed doors.

67. CW6 worked as a Therapeutic Specialist at Gilead from March 2003 until January 2006. CW6 marketed HIV pharmaceuticals to hospitals, clinics, and physicians in the Brooklyn and Queens, New York area. She/he recalled that the Company's VP of Sales, Meyers, was engaged in highly unethical behavior and served as a conduit for directives from the highest levels of the Company.

68. With regard to off-label uses, CW6 recalled receiving and using off-label materials "all the time" in sales presentations, and stated the Company's sales representatives were routinely provided with papers or studies supporting one or another off-label use. She/he stated off-label marketing was known by everyone to comprise a core component of the Company's marketing and sales for Viread. For example, CW6 stated that in 2003 and 2004, it was well-known through the Company's sales representatives that marketing to Hepatitis B patients was an alternative means of marketing and selling Viread.

69. CW6 stated the use of off-label materials in sales presentations was prevalent for Viread, and confirmed that off-label materials were included in a binder distributed within the Company to sales representatives. To ignore those off-label materials would be to consign yourself to a far more limited (albeit legal) market. She/he stated many conferences held around the world generated abstracts and other materials describing small or informal studies and other information relating to the use of Viread for Hepatitis or treatment naïve patients. These studies were often made

up of only 30 to 40 patients, or were Phase II studies. CW6 stated Company sales people would "use those studies to suggest whatever we were trying to convey at the moment."

70. CW6 recalled that although many off-label materials had "For Educational Purposes" stamped on the bottom, it could be easily covered up when reproducing the document. In fact, she/he said that such a designation was a "joke" and that her/his boss was well aware how such materials were used and why. One reason was enormous pressure to make sales. CW6 stated that the Viread sales staff was driven by Company management to improve sales numbers for publication to a national marketplace.

71. Among other things, CW6 has knowledge of how off-label materials were presented to doctors during sales calls, and how the Company sought to take advantage of treatment naïve patients before receiving FDA approval for that indication because treatment naïve patients offered the longest potential users of Viread. For example, she/he recalled the Company's sales force sold Viread first line (*i.e.*, to treatment naïve patients) all the time and that if they did not do so, they would have been fired from Gilead. CW6 recalled using non-FDA approved study data to promote Viread as a first-line therapy to treatment naïve patients, and stated that easily 70% of her/his Viread sales were attributable to off-label treatment naïve patients.

72. CW7 was a former Therapeutic Specialist and Trainer for Gilead in Dallas, Texas who was with the Company from prior to 2002 until approximately 2006. CW7 estimated that, with regard to Hepatitis-B infected patients, 10% of her/his total Viread sales were off-label to treating physicians. CW7 believes the Company also was promoting Viread off-label in the pediatric population. CW7 estimates that her/his sales to a pediatric population were about 10% of her/his total sales. Thus, in these two patient segments alone, 20% of CW7's total Viread sales were completely off-label. While CW7 did not actively pursue off-label sales in other areas, she/he stated that other sales representatives were feeling pressure to engage in off-label marketing to boost their sales. CW7 stated that a key culprit in getting the off-label message out was Rich, Gilead's Regional Director of Sales for the South.

73. CW8 was a former Gilead Therapeutic Specialist from April 2003 until mid-2008. CW8 recalls that early in the launch of Viread, sales representatives were instructed to promote

Viread to Hepatitis B doctors because it was active. She/he explained that "active" in a pharmacologic context means that a chemical agent has activity against a certain infective agent, and Hepatitis B was an infective agent. CW8 recalled that because there was data showing Viread was active against Hepatitis B, Gilead's training materials supported that it was active and managers informed the sales force that it was part of management's expectation that this information would be communicated on sales calls. The indisputable fact that Viread had not been cleared by the FDA for this use was not part of the discussion; the discussion was that the product was "active." CW8 also stated that co-infected patients with Hepatitis-B and HIV were considered to be easy sells at Gilead. She/he recalled that Martin would refer to Viread as a miracle product all the time at meetings, which suggested to those listening that they could use that language out in the field when selling Viread to doctors. CW8 recalled that Gilead's sales force had "little if any regulatory training" and was not discouraged from repeating off-label medical claims espoused by Martin at sales meetings.

FACTUAL DETAIL UNDERMINING THE TRUTH OF DEFENDANTS' CLASS PERIOD REPRESENTATIONS

A. Gilead's Fraudulent Off-Label Marketing Campaign

FDA Prohibitions

74. The Federal Food, Drug, and Cosmetic Act, and its implementing regulations, 21 U.S.C. §301, *et seq.*, set forth the manner in which a pharmaceutical manufacturer is permitted to market and promote its products. According to these guidelines, a pharmaceutical manufacturer may only promote an FDA approved drug consistent with the contents of the drug's official package labeling (the "Package Labeling"). *See* 21 C.F.R. §202.1. To ensure that pharmaceutical companies comply with these rules, the FDA monitors and enforces the Federal Food, Drug, and Cosmetic Act through its Division of Drug Marketing, Advertising, and Communications (the "DDMAC").

75. In their public statements, Defendants emphasized that their business plan placed great importance on their careful compliance with these federal and state regulations. For example, in Gilead's 2002 10-K, Defendants stated:

> In the U.S., drugs are subject to rigorous FDA regulation. The Federal Food, Drug and Cosmetic Act and other federal and state statutes and regulations govern the

> testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our products. . . . We are required to demonstrate the safety and effectiveness of products we develop in each intended use through extensive preclinical studies and clinical trials in order to obtain regulatory approval of these products.

76. Based upon FDA rules and regulations, each of Gilead's FDA-approved drugs is accompanied by prescribing information provided to doctors prescribing and patients using the drug (the "Prescribing Information"). The FDA approves every word of the Prescribing Information, which is part of the Package Labeling. The Package Labeling thus provides information about the drug, its approved and intended uses, and a description of its side effects. The Package Labeling is vital to a physician's determination of whether to prescribe the drug. Indeed, the Physician's Desk Reference ("PDR"), the standard guide to prescription drugs for physicians and other healthcare professionals, reproduces the FDA approved prescribing information and labeling to allow physicians, pharmacists, and other medical professionals to correctly use prescription drugs to treat their patients.

77. Because the information contained in the Package Labeling is based upon medical studies and scientific data submitted to and approved by the FDA, it is used by physicians to determine whether a drug can be effectively used and safely tolerated by their patients. The FDA prohibits pharmaceutical manufacturers' sales and marketing representatives from promoting prescription drugs with information not found in the Package Labeling. As such, use of non-FDA approved materials is referred to as "off-label" marketing.

78. For example, it would be considered off-label for a company to market a FDA-approved HIV/AIDS drug as also being effective for fighting Hepatitis B infection (which, as discussed in more detail below, Gilead illegally did with Viread) if such use of the drug had not been reviewed and approved by the FDA and included in the Package Labeling.[2] So long as the Package

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[2] Hepatitis B is a serious disease caused by a virus that attacks the liver. The virus, which is called hepatitis B virus or HBV, can cause lifelong infection, cirrhosis (scarring) of the liver, liver cancer, liver failure, and death.

Labeling lacks information regarding the HIV drug's ability to fight Hepatitis B infection, the company's sales representatives are not permitted to speak about this to their customers.

79. The only exception to this rule is if a physician or other medical professional ***specifically requests such information first***, via a signed written form. For example, a physician may be treating a patient who has both HIV and Hepatitis B co-infection. While treating the patient, the physician may notice that the patient's HIV medication appears to positively impact the patient's Hepatitis B infection symptoms. In such a situation, if the doctor submits a written request to the drug manufacturer, typically by utilizing a Gilead inquiry form (the "Inquiry Form"), the drug manufacturer may provide the doctor with results of studies which detail the drug's interaction with Hepatitis B infection, even if those results are not FDA approved or found in the Package Labeling. *See* Exhibit A attached hereto (a true and correct copy of a Gilead Inquiry Form). The company sales representatives are not permitted to initiate conversation or promote this to their customers.

80. Without such a request it is a direct violation of FDA rules and regulations for a drug company to provide its customers with off-label information. And yet, according to the Confidential Witnesses, Defendants encouraged and expected Gilead's sales and marketing staff to do exactly that, and then – after the fact – obtain an Inquiry Form to create the appearance of propriety.

81. Moreover, Defendants trained Gilead's sales force to purposely misuse off-label information in order to boost sales and gain an advantage over competitors. Indeed, as set forth below, the Company specifically used its training department to deliver the Company's off-label message for Viread to Gilead's sales force.

82. While companies are permitted to promote their products with information found in the Package Labeling, Gilead, as part of its scheme to artificially boost Viread sales, repeatedly exceeded this recognized limitation set by the FDA to promote Viread. Specifically, since prior to the launch of Viread, Gilead implemented a scheme to promote and market Viread with off-label, false, and misleading statements in violation of the Federal Food, Drug, and Cosmetic Act. In order to gain market share, artificially increase perceived demand, and increase sales, Gilead officers, executives and clinical personnel, with the express knowledge and approval of the Individual Defendants, routinely and consistently provided Gilead's sales and marketing team with off-label

information and encouraged, expected, and directed them to use it to sell Viread even without the written request of a medical professional. Gilead's sales and marketing strategies, as well as its entire corporate culture, rested heavily on selling Viread by way of off-label, unapproved information.

83. According to CW1, in an effort to win FDA approval for Viread, Gilead submitted to the FDA a book of Viread clinical data and information, entitled the FDA Advisory Committee Briefing Document (the "FDA Briefing Document"). *See* Exhibit B attached hereto (a true and correct copy of the FDA Briefing Document). The FDA did not include all of the information found in the FDA Briefing Document in Viread's Package Labeling. For example, the FDA Briefing Document contained information regarding Viread's impact on bone density and the incidence of bone fracture resulting from Viread use. Because the FDA withheld such information from the Package Labeling, Gilead's sales team was prohibited from marketing Viread as being superior to other HIV drugs with regard to bone density issues.

84. CW1 confirmed that Gilead submitted the FDA Briefing Document to the FDA because, in September 2001, while attending a company-wide national meeting in Miami, Florida (the "Miami National Meeting") CW1 and other members of Gilead's sales and marketing team viewed, via teleconference, Gilead's executives and clinical researchers presentation to the FDA Advisory Committee in Washington, D.C. In addition, while at the Miami National Meeting, CW2 confirmed the substance of the materials Gilead's executives covered during the teleconference.

85. According to both CW1 and CW2, among those present at the Washington, D.C. FDA presentation were Defendants Martin, Perry, Lee, and Milligan. All in attendance at the FDA briefing were aware that Gilead's sales and marketing staff was watching the presentation via teleconference at the Miami National Meeting. CW4 also attended the meeting with FDA representatives in Washington, D.C., and recalls Defendants Martin and Bischofberger being in attendance. CW4 stated Gilead had extensive data to support an "experienced" indication for Viread, but expected to receive naïve indication approval at the FDA meeting. Viread, however, was only initially approved as an "experienced" treatment option.

86. The Miami National Meeting teleconference was attended by, among others, Meyers, Weisbrich, and Fletcher. According to CW1 and CW2, the purpose of the teleconference was to allow Gilead's salespeople and marketing department to become familiar with the FDA Briefing Document and related materials in order to market Viread, regardless of the FDA's approval and indication assigned to Viread.

87. After making their presentation to the FDA, Gilead's officers, executives, and clinical personnel, including Inouye and Defendants Martin, Milligan, Perry, and Bischofberger traveled to the Miami National Meeting already in progress. CW1 and CW2 specifically recall that, while at the Miami National Meeting, Gilead representatives provided them and other Gilead sales and marketing staff with off-label marketing information and, with a "wink and a nod," instructed them to use it to sell Viread. CW1 and CW2 specifically recall Defendant Martin attending those same meetings in Miami and physically being at meetings during which Gilead's sales and marketing team members were given their marching orders.

88. Importantly, at the time of the FDA presentation, according to CW1, the FDA had not approved any of Gilead's clinical studies or theories for Viread. Thus, everything discussed at the Miami National Meeting, and not later included in the Package Labeling, was off-label.

89. Although Gilead's clinical researchers created the FDA Briefing Document for the FDA, the entire book was intentionally provided to at least some of Gilead's sales and marketing team at the Miami National Meeting in September 2001. DelloStritto, CW1's supervisor and Gilead's Regional Director for the Mid-West, instructed CW1 to make numerous copies of the FDA Briefing Document and distribute it to various members of Gilead's Viread sales and marketing team. According to CW1, the sole purpose of Gilead instructing him or her to do so was to provide it to Gilead's sales force so that they could market Viread with off-label information in order to increase sales.

90. Thus, even before the FDA approved Viread one month later (October 2001), Gilead representatives and employees planted the seeds of fraud by circulating off-label information to artificially boost sales of Viread.

91. In that regard, CW4 stated that despite the lack of approval for Viread for treatment naïve HIV patients, marketing Viread as a treatment option for treatment naïve patients was very much a part of the Company's strategy. For example, CW4 recalls that during the role play sales training sessions that she/he attended, including at the Company's national sales meetings, one question that was posed to Therapeutic Specialists as part of their training and preparation (as if the question was coming from a customer or infectious disease practitioner) was "why should I not use it [Viread] for naïve patients?" The Therapeutic Specialists were trained to answer the question in a manner that effectively informed the HIV doctor that he or she should use Viread for a naïve indication and that there was no reason to not use Viread for a naïve indication. CW4 stated this strategy to market Viread for a naïve indication, despite the lack of FDA approval for such during the Class Period, came down from the highest levels of Company management, including from Defendant Martin.

92. Similarly, CW6 stated the Company sought to take advantage of the treatment naïve patient group because it offered the patients who would take Viread for the longest period of time (and thus sustain Viread sales). She/he stated the Company and its sales staff always pushed for treatment naïve patients because they would remain on their first regimen of HIV drugs for a long period of time. Gilead did this despite the fact that, at the time, there was no indication for use of Viread as a first-line HIV therapy. CW6 stated the Company sold Viread as an initial therapy all the time, and that if members of the sales staff did not do so, they would be fired. CW6 recalled, among other things, using various non-FDA approved study data to support Viread's use in treatment naïve patients and that the sales staff had visuals, marketing pieces, and visual aids of off-label information from the ongoing studies.

93. Gilead and the Individual Defendants, at all relevant times (including prior and subsequent to the Class Period), knew that off-label marketing of Viread was improper. Hence, to cover its tracks, Gilead often combined its "wink and a nod" directives to its sales force (including providing off-label materials for use by its sales force) with meaningless, perfunctory reminders that such off-label materials should not be provided to Gilead's customers. CW4 confirmed that Defendants tried to cover their tracks, knowing that outward directives to promote Viread for off-

label use would get them in trouble. Instead, CW4 said there was a more discreet effort to implement the strategy to promote Viread for off-label use.

94. Gilead, in effect, tried to cover its tracks by directing, expecting, and encouraging off-label marketing but combining those directives with a paper trail that could be used in the event they were ever caught. Since Gilead's scheme of illegal marketing has now been exposed, and Gilead has been caught, it will no doubt turn to its paper trail in order to attempt to avoid liability. This Court should anticipate this and not be fooled.

95. One example is that one of Gilead's common tactics was to circulate to its sales staff a cover memorandum with off-label materials attached. The body of the cover memorandum would say that the materials were for "internal use only," but the actual off-label materials would conspicuously not contain any such limiting language. *See* Composite Exhibit C attached hereto (true and correct copies of internal Gilead documents demonstrating this practice). The sales and marketing staff was then directed, expected, and encouraged to remove the cover memorandum and use off-label materials to promote Viread. Indeed, CW1 recalls being told by DelloStritto not to let such off-label materials get into the hands of unintended recipients because it was illegal for CW1 and other Therapeutic Specialists to use that information.

96. CW3 stated that while she/he worked as a Therapeutic Specialist, materials were presented and distributed to the Gilead sales force at national and regional sales meetings, and the materials contained facts about the efficacy of Viread as a drug for treatment naïve patients, and for treatment of Hepatitis B (namely co-infected patients). CW3 also stated the sales force received updates on studies that supposedly validated the use of Viread for off-label indications. This experience was echoed by CW1, CW2, CW4, CW5, and CW6. Similarly, CW8 recalled receiving training materials that included off-label uses. While CW3 was not directly told to use the marketing materials she/he received, she/he emphasized that "everything was provided to the reps that they needed" to promote Viread off-label and there was widespread, covert encouragement by senior management for Therapeutic Specialists to use such data in sales calls – which they did throughout CW3's tenure. For example, CW3 stated sales of Viread for use by treatment naïve patients represented a "large portion" of the sales of Viread before and during the Class Period, which

resulted from Defendants' off-label marketing scheme. While CW3 stated Defendants' off-label sales strategy was definitely covert, it also definitely spanned the ranks of the sales and marketing organization and defined the culture of the Company.

97. CW3 recalled Defendant Martin routinely speaking off-label about Viread at internal and external meetings. CW3 attended meetings with the key opinion leaders in her/his territory, along with Martin. She/he believed there were at least 3 meetings in the Seattle, Washington area while CW3 worked as a Therapeutic Specialist during which Martin spoke off-label about Viread to key opinion leaders. In particular, Martin recounted results of a Viread study in which a certain type of monkey had been injected with SIV or HIV, and that approximately 48 hours after being injected with the virus, the monkeys were given a high dosage of Viread and subsequent tests showed they did not contract the virus with which they were injected. Martin used these study results to promote Viread off-label and to effectively suggest Viread had increased potency beyond what was indicated in its Package Labeling.

98. In December 2001, Gilead hosted a weeklong national meeting for its employees at the Phoenician Hotel in Scottsdale, Arizona (the "Arizona National Meeting"). CW1 and CW2 attended this meeting, the purpose of which was to celebrate the FDA's approval of Viread and ready the Company for an aggressive and illegal marketing campaign using off-label materials.

99. During the Arizona National Meeting, CW1 and CW2, along with numerous other members of Gilead's sales and marketing staff, attended several Viread marketing presentations. CW1 and CW2 specifically recall Defendants Martin, Milligan, and Perry attending these meetings. During these marketing presentations, Gilead provided the sales staff with updates regarding ongoing Viread clinical trials, the results of which, until approved by the FDA, were off-label.

100. In addition, CW1 and CW2 recall attending Arizona National Meeting presentations during which they, and numerous other Gilead sales and marketing staff, received updates concerning various clinical trials, including Study 903 and Study 907. They also participated in discussions regarding Viread's resistance profile and potential use to combat Hepatitis B infection, even though Viread had (until very recently) never been approved to treat Hepatitis B infection. The

FDA did not include any of this information in Viread's Package Labeling and, therefore, it was considered off-label at the time it was presented and throughout the Class Period.

101. The FDA Briefing Document described Study 903 even though it was incomplete. Under the heading "Plans for Further Development," the FDA Briefing Document states that Gilead designed Study 903 to evaluate the safety and efficacy of Viread versus Stavudine, another HIV/AIDS drug manufactured by one of Gilead's competitors. According to the FDA Briefing Document, the forty-eight week data from Study 903 was expected to be available in early 2002. Study 903 was testing Viread as a first-line or initial antiretroviral therapy regimen for treatment "naïve" patients. The success of the study was necessary for Gilead to substantially increase Viread sales by expanding its indication and the patient market of eligible Viread users. ***Thus, by providing Gilead's sales and marketing team with Study 903 information in December 2001, Gilead was providing them with off-label information on a study that was not even scheduled to reach completion until early 2002. The sole purpose of providing Study 903 to Gilead's sales and marketing team was to arm them with data that could be used to sell Viread off-label as a first-line therapy to treatment naïve patients and increase sales***. As discussed in more detail below, Defendants' scheme worked.

102. As with Study 903, Gilead included Study 907, also off-label, in the FDA Briefing Document. Gilead designed Study 907 to evaluate the efficacy of Viread in a large population. Study 907 involved 552 patients who received varying doses of Viread and were deviating from their then-current intake levels of other HIV/AIDS drugs. Gilead designed Study 907 to select patients who had experience with other HIV/AIDS drugs and had a detectable viral load. In the FDA Briefing Document, Gilead described the results of Study 907 as demonstrating that Viread had significant anti-HIV activity.

103. Gilead encouraged the sales and marketing staff to use updates on Study 907 in order to discuss the long-term safety of Viread in patients also taking other HIV/AIDS medications. According to CW1 and CW2, this off-label long-term safety data offered a clear advantage for marketing Viread because many HIV drugs are new to the marketplace and thus lack any long-term data. Accordingly, despite the off-label status of these studies, Defendants encouraged, expected,